

Serial No.: 10/075,970

### REMARKS

#### Status of the claims

Claims 1, 3, 5-7, 9-21, 46 and 47 are pending in the application.

#### Rejection over Eury and Bolz

Claims 1, 3, 5, 6, 9-21, 46 and 47 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Eury US 5,443,458 in view of Bolz et al. US 6,287,332 (Bolz). This rejection and its accompanying remarks are respectfully traversed.

In the response to non-final rejection filed November 5, 2007, applicant presented detailed arguments against the propriety of this rejection. It is respectfully requested that those arguments be considered incorporated by reference into this response. The following remarks are directed mainly to the Examiner's **Response to Arguments**.

The Examiner's sole remark is that the limitation "wherein the covering material substantially controls the rate at which the inner core material becomes flexible upon contact with bodily fluids" is "a functional limitation." However, it is well settled that "there is no prohibition of the use of functional language to distinguish over the prior art," and in this case the controverted limitation actually describes a property of the claimed structure, not merely a function. *In re Swinehart*, 439 F.2d 210, 169 U.S.P.Q. 226, 228 (CCPA 1971). On the issue of functional limitations generally, see *In re Fuetterer*, 319 F.2d 259, 138 U.S.P.Q. 217, 222 (CCPA 1963). As stated previously, and repeated here for emphasis, the structure required to give rise to the property or function recited is the *concept* at the heart of the present invention which is completely lacking from the references (e.g., in Eury, the laminated outer layers are drug releasing layers, rather than layers that control the rate at which an inner core material becomes flexible upon contact with bodily fluids).

In addition to the property of thickness of the covering material mentioned as a rate controlling property in the previous response, there must be taken into account its chemical composition, which will determine, for example, its rate of biodegradation and its ability to act as a diffusion barrier to body fluids. See paragraphs [0032], [0033] and [0036] to [0039] of the specification, for example.

Serial No.: 10/075,970

**Claims 10-13, 17 and 18**

Furthermore, as pointed out previously, no disclosure in Eury or Bolz suggests, for example, an inner core material comprising a ceramic core as claimed in claim 10, a monofilament core or a multifilament core as claimed in claims 11-13, or an additional coating layer, which may contain at least one therapeutic agent as claimed in claims 17 and 18.

The Examiner's rejection stated that "Eury discloses that various modifications may be made." There is no explanation provided, however, as to what reference disclosures suggest the specific "modifications" required by Applicant's claims or why one of ordinary skill in this art would have been motivated to make them, with a reasonable expectation of success. *In re Jones*, 958 F.2d 347, 351, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992), *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ 1596, 1598-99 (Fed. Cir. 1988), *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (B.P.A.I. 1986).

For example, with respect to claim 10, there is no teaching or suggestion that the Examiner's rationale to use a metallic material as an inner core in Eury (improved mechanical properties) is relevant to ceramic cores. With respect to claims 11-13, a monofilament core or a multifilament core as claimed is far removed from the plate-like structures of Eury and far beyond a "matter of design choice."

It would appear that the examiner is requesting a showing of unobvious results before a *prima facie* case of obviousness has been made out. That misplaces the burden, which initially is on the examiner to make out a *prima facie* case. *In re Piasecki*, 745 F.2d, 1468, 1471-72, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984), *Ex parte Obukowics*, 27 U.S.P.Q.2d 1063, 1065 (BPAI 1992).

The foregoing remarks regarding functional language apply as well to claims 10-13, 17 and 18, which depend from claim 1.

**Claims 46 and 47**

In the **Response to Arguments** section, the examiner has not commented on new claims 46 and 47, which recite a specific range of time in which the inner core will become completely biodegradable and to remain sufficiently rigid to serve the purpose of the invention. In the explanation of the rejection, the Examiner concludes, with no support, "it would have been

Serial No.: 10/075,970

obvious" because "the general conditions" of the claims were known, and the present claims represent "optimum or workable ranges." That conclusion overlooks the fact that the central concept of the present invention was not disclosed in the prior art.

In the absence of such disclosure, there can be nothing to optimize within the prior art. *In re Schek*, 465 F.2d 904, 907, 175 U.S.P.Q. 93, 95 (C.C.P.A. 1972). It would be obvious to optimize a "known result effective variable." *In re Antonie*, 559 F.2d 618, 620, 195 U.S.P.Q. 6, 8 (C.C.P.A. 1977). However, in this case the concept and the result themselves are not disclosed in the prior art, so it cannot be said that there is a "known result effective variable" to optimize.

The foregoing remarks regarding functional language apply as well to claims 46 and 47, which depend from claim 1.

Reconsideration and withdrawal of this rejection under 35 U.S.C. 103(a) are respectfully requested.

#### **Rejection over Eury, Bolz and Langer**

Claim 7 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Eury in view of Bolz and Langer et al. US 6,160,084 (Langer). This rejection and its accompanying remarks are respectfully traversed.

It is respectfully requested that the remarks concerning this rejection in applicant's prior response be herein incorporated by reference. No additional explanation of the basis for this rejection has been presented in the final rejection. Thus, applicant stands on the previous response.

Reconsideration and withdrawal of this rejection under 35 U.S.C. 103(a) are respectfully requested.

#### **CONCLUSION**

Applicant submits all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

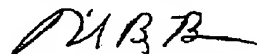
Serial No.: 10/075,970

**FEES**

If there are any fees due and owing in respect to this amendment, the Examiner is authorized to charge such fees to deposit account number 50-1047.

Attorney for Applicant  
Mayer & Williams PC  
251 North Avenue West, 2<sup>nd</sup> Floor  
Westfield, NJ 07090  
Tel.: 703-433-0510  
Fax: 703-433-2362

Respectfully submitted,



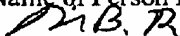
David B. Bonham  
Registration No. 34,297

**Certificate of Facsimile Transmission**

I hereby certify that this document and any document referenced herein is being sent to the United States Patent and Trademark office via Facsimile to: 571-273-8300 on 3/10/2008.

David B. Bonham

(Printed Name of Person Mailing Correspondence)



(Signature)